95, 62, 55 days respectively. Most of the application represented new generic drugs (252, 213, 264, 225 pieces). Between 2005–2008 the average delay for new generic drugs was 75, 64, 58, 56 days. **CONCLUSIONS:** The introduction of EU transparency directive provided a strong regulatory framework for decision-making process on drug reimbursement. In the simplified procedure we did not found significant differences in time delay of decision according to submission categories. However, in 2007 the average delay significantly decreased compared to previous years.

PHP14

A POLICY ANALYSIS OF THE PORTUGUESE GENERIC MEDICINES MARKET

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OBJECTIVES: This study aims to conduct a descriptive analysis of the policy environment surrounding the generic medicines retail market in Portugal. The policy analysis focuses on supply-side measures (i.e. market access, pricing, reference-pricing and reimbursement of generic medicines) and demand-side measures (i.e. incentives for physicians to prescribe, for pharmacists to dispense and for patients to use generic medicines). **METHODS:** The policy analysis was based on an international literature review. Also, a simulation exercise was carried out to compute potential savings from substituting generic for originator medicines in Portugal using IMS Health data. **RESULTS:** Portugal has developed a successful generic medicines market by increasing reimbursement of generic medicines (until October 2005), by introducing a reference-pricing system, by encouraging physicians to prescribe by international non-proprietary name (INN), and by allowing generic substitution by pharmacists. However, the development of the generic medicines market has been hindered by the existence of copies, pricing regulation, certain features of the reference-pricing system, weak incentives for physicians to prescribe generic medicines and a financial disincentive for pharmacists to dispense generic medicines. Increased generic substitution would be expected to reduce public expenditure on originator medicines by 45%. **CONCLUSIONS:** The development of the Portuguese generic medicines market has mainly been fuelled by supply-side measures. To support the further expansion of the market, policy makers need to strengthen demand-side measures inciting physicians to prescribe, pharmacists to dispense and patients to use generic medicines.

PHP15

BIOSIMILARS: HGH TO TNFS, HOW WILL PAYERS RESPOND?

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OBJECTIVES: Biologic agents have helped revolutionize the treatment of a number of chronic and acute diseases. These highly valued products have also placed a significant cost burden on health care systems. For example, the average annual price of TNFs in the EU5 is €12,400 per patient (MSP). Payers, understandably, are eagerly awaiting the arrival of biosimilars. However, because of their biologic nature, biosimilars are not exact copies of the drugs they seek to emulate. This important difference between biosimilars and traditional generics has resulted in greater requirements for regulatory approval and has led some markets to take positions on their (non) interchangeability. Given these dynamics, this research explores likely price discounts of anticipated biosimilars, provides an analysis of what lessons can be taken from traditional generics and forecasts how biosimilars might change the standard of care for their respective therapy areas. **METHODS:** Review the EMEA data requirements and current prices of biosimilars on the European market. Review current biosimilar environment, including a review of current biosimilar pricing and uptake. Limited primary research. **RESULTS:** The most commonly anticipated price discount of biosimilars is 20–30% to the parent drug. This expectation is largely driven by past experience with biosimilar human growth hormones, erythropoietins and G-CSFs. **CONCLUSIONS:** Biosimilars will introduce a new competitive dynamic to the biologic market. However, because of the considerably higher cost of bringing biosimilars to market and the potential to differentiate biosimilars, the initial price discount of biosimilars will be more similar to a me-too like pricing strategy as opposed to what has been seen with competitive generic markets (e.g. fluoxetine). Importantly, even at a 20–30% discount, there will be sufficient cost-savings to encourage the use of biosimilars over their parent drug.

PHP16

PARALLEL TRADE OF PHARMACEUTICALS IN POLAND

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OBJECTIVES: To prepare detailed analysis of parallel trade of pharmaceuticals in Poland and to build a model calculating direct and indirect savings resulting from this phenomenon. **METHODS:** Diligent analysis of parallel trade based on data provided by IMS Health and gathered from The Polish Office for Registration of Medical Products, Medical Devices and Biocidal Products preceded by systematic literature review. **RESULTS:** Parallel import (PI) of pharmaceuticals in Poland has been possible since Poland became an EU member in May 2004. Since that date the PI licences have been granted for 352 medicines in Poland (73% prescription medicines, 20% OTC, 5% hospital and 2% veterinary). Currently, there are 18 parallel traders operating on the Polish market although only 5 have a significant share. Pharmaceuticals offered by parallel importers in Poland are exported mainly from Greece (33%), the Czech Republic (17%), France (12%), and the UK (12%). The share of parallel trade in total pharmaceutical market reached 0.5% in January 2009 compared to 0.3% in December 2007. The sales value from parallel import was PLN 82 million in 2008. Available analyses prove that medicines from parallel trade are cheaper than original products in Poland by about 20 to 60%. Up to now, there were no scientific studies of savings, resulting from parallel import in Poland. Detailed study on this topic is planned in cooperation with recognized European experts on parallel trade—University of Southern Denmark researchers. **CONCLUSIONS:** Parallel import is expected to grow in the next few years in Poland. Therefore, it is necessary to implement a reliable model of support for parallel importers by means of appropriate directives introduced by the Polish Government. In order to convince decision-makers that parallel import could be a source of substantial savings a detailed study is going to be conducted according to methodology mentioned above.

PHP17

CAN ELECTRONIC NOTIFICATIONS ABOUT SUBSTITUTES CHANGE PHYSICIANS' DRUG PRESCRIPTION HABITS? DEFINITELY YES!

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OBJECTIVES: Diffusion of electronic patient record (EPR) systems is almost universal in ambulatory medical services in Israel. The drug prescription module of the most widely-used EPR system has an intervention capacity of electronically notifying physicians about generic or therapeutic drug substitutions. This notification is triggered when the physician's first choice of a prescribed drug does not meet preferences of the health maintenance organization (HMO). The objective of this paper was to study whether and how such an intervention can influence physicians' drug prescription habits and help contain costs. **METHODS:** We monitored system use for 40 consecutive weeks in the second largest HMO in Israel, covering more than 1.2 million prescriptions, and recorded physicians' willingness to comply and prescribe a substitute drug in response to the system's notification. **RESULTS:** Findings show that *electronic notifications about substitutes can change physicians' drug prescription habits toward compliance with HMO preferences*. Higher physician compliance was found for generic substitutes than for therapeutic substitutes. Moreover, compliance was based on a cognitive decision process triggered upon notification. Examining the notification and deciding whether to comply or not lasted 2 to 5 seconds, hence not time consuming. An increase in compliance over time, until stabilization, was also observed. The direct financial savings on drug expenditures were estimated at 4.7%, mostly for chronic drugs, implying long-term saving. **CONCLUSIONS:** The results show that embedding notifications about substitute drugs in an EPR's drug prescription module can be effective and impact drug prescription behavior toward compliance, yet this compliance is context-dependent rather than automatic. In addition, long-term cost containment can be achieved without decreasing the quality of care.

PHP18

COMPARATIVE ANALYSIS OF THE IMPACT OF POSITIVE DRUG LIST SYSTEM BETWEEN NEW DRUGS VS INCREMENTALLY MODIFIED DRUGS IN SOUTH KOREA

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OBJECTIVES: In Korea, Positive List System(PLS) was introduced as a drug listing system in Jan 2007. This study aimed to comparatively analyze the impact of the PLS introduction on the listing of incrementally modified drugs(IMD) and new drugs(ND). **METHODS:** Database for new drug coverage assessment was established based on selective drug listing assessment data from HIRA website and MOHW reference publications. They analyzed the two-year drug listing data submitted to the Drug Review and Evaluation Committee (2007.1.–2008.12) since the introduction of PLS. SAS version 9.1 was used for descriptive analysis and logistic regression in statistical analysis. **RESULTS:** After the introduction of PLS, success rate of coverage decision was 74.6% and 50.6% for IMD and ND, respectively; for drug price agreement rate, 73.6% and 85.0%; for final drug listing rate, 54.9% and 43.0%, placing IMD higher than ND. Time to coverage decision for IMD and ND was 109.0days and 155.7days, respectively; time to drug listing was 192.9days and 260.0days, respectively, indicating much shorter time to decision and listing for IMD than general ND. The final listing rate was 52.1% for multinational pharmaceutical companies while being 48.6% for domestic drug makers. The factors having the largest influence on insurance listing were cost-effectiveness for IMD and financial impact for ND. **CONCLUSIONS:** The introduction of PLS resulted in higher coverage rate and shorter time to final listing for IMD compared to ND. The factors affecting the insurance listing differed between IMD and MD, with cost-effectiveness being the major factor for IMD.

PHP19

APPLYING "VALUE BASED" PRICING TO REGENERATIVE MEDICINE BASED PHARMACEUTICALS

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OBJECTIVES: Recent advances in embryonic stem cell based therapies are moving regenerative medicine based products into clinical trials and closer to entering the pharmaceutical arena. As these therapies edge closer to entering the market, it is important that appropriate health technology assessments are in place to deal with these new market entrants. Both autologous and allogenic products are under development, however, this analysis will focus on allogenic products and the challenges they will face. Allogenic products are derived from cells or tissues and likely to be marketed "off the shelf," similar to conventional biopharmaceutical products. While regulatory